K053562

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JUN 23 2006

510(k) SUMMARY

Tissue Science Laboratories, plc
Zimmer® Collagen Repair Patch

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Angela L. Bunn, RAC
Tissue Science Laboratories, plc
1141 Clark Street
Covington, Georgia 30014
USA
Tel: (678) 342 – 7808
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Email: abunn@tissuescience.com

Contact Person: Angela L. Bunn, RAC

Date Prepared: 14th June 2006

Name of Device and Name/Address of Sponsor

Tissue Science Laboratories, plc
7th Floor, Victoria House
Victoria Road
Aldreshot
Hampshire GU11 1 EJ
United Kingdom

Trade Name

Zimmer® Collagen Repair Patch

Common or Usual Name

Surgical Mesh

Classification Name

Surgical Mesh

Predicate Devices

- Tissue Science Laboratories, plc, Permacol® Surgical Implant (K021056)
- DePuy, Inc., Restore® Orthobiologic Soft Tissue Implant (K031969)
- Organogenesis, Inc., CuffPatch™ (K042809)

Intended Use

Zimmer® Collagen Repair Patch is intended for the reinforcement of soft tissues repaired by sutures or suture anchors, during rotator cuff repair surgery.

Zimmer® Collagen Repair Patch is not intended to replace normal body structure or provide the full mechanical strength to repair the rotator cuff. Zimmer® Collagen Repair Patch reinforces soft tissue and provides a scaffold that is eventually incorporated into the patients own soft tissue.

Technological Characteristics and Substantial Equivalence

Zimmer® Collagen Repair Patch is substantially equivalent to the predicate devices because it has the same intended use and very similar technological characteristics.

Performance Data

Biocompatibility and bench studies have been completed and support the safety and effectiveness of Zimmer® Collagen Repair Patch for its intended use.

The biocompatibility test results show that the material used in the design and manufacture of the devices are non-toxic and non-sensitizing to biological tissues consistent with their intended use. Test results demonstrate that the materials chosen and the design utilized in manufacturing the Zimmer® Collagen Repair Patch will meet the established specification necessary for consistent performance during its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2009

Covidien
% Ms. Angela L. Bunn, RAC
Associate Manager
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K053562
Trade/Device Name: Collagen Repair Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: April 24, 2006
Received: April 25, 2006

Dear Ms. Bunn:

This letter corrects our substantially equivalent letter of June 23, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K053562

Device Name: Collagen Repair Patch

Indication for Use:

Collagen Repair Patch is intended for the reinforcement of soft tissues which are repaired by sutures or suture anchors, during rotator cuff repair surgery. Collagen Repair Patch is not intended to replace normal body structure or provide the full mechanical strength to repair the rotator cuff. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone, provide biomechanical strength for the rotator cuff repair. Collagen Repair Patch reinforces soft tissue and provides a scaffold that is eventually incorporated into the patients own soft tissue.

Prescription Use √ AND/OR Over-The Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of General, Restorative, and Neurological Devices

510(k) Number K053562